

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA	:	CRIMINAL ACTION
	:	
v.	:	
	:	CRIM. NO. 21-132
MURTY VEPURI, et al.	:	(MAG. NO. 21-mj-1220)

**GOVERNMENT’S MOTION TO MODIFY THE COURT’S
ORDER RELATED TO FILTER TEAM COMPOSITION**

The government respectfully requests that the Court modify its Order related to the Filter Team’s composition to permit the government to have the technical expertise to properly address KVK’s numerous claims of privilege and protection. Specifically, the government requests that it be permitted to add one or more attorneys from the Food and Drug Administration’s Office of Chief Counsel (“OCC”) to assist in the Filter Team’s evaluation of KVK’s claims that certain materials should not be released to the Prosecution Team because they are subject to attorney-client privilege or work product protection. For the reasons set forth below, this technical assistance is necessary to efficiently, thoroughly, and accurately evaluate the merits of KVK’s claims, and it would not result in any unfair prejudice to KVK. A proposed order is included in this motion.

1. On November 3, 2021, this Court entered an order governing filter protocols for the review and disclosure of materials seized from defendant KVK pursuant to three search warrants. *See* Order, ECF No. 87.

2. As part of the Order, the Court stated that the Filter Team would be “comprised of Department of Justice (‘DOJ’) attorneys, contract attorneys acting under the supervision of DOJ attorneys, and designated support staff acting at their direction, none of whom is a member of the Prosecution Team.” *Id.* at 1. The motion practice leading to the Order did not raise the question of whether FDA personnel could serve on the Filter Team because, at the time, the government did not believe that FDA technical assistance would be necessary. Consequently,

the Order does not expressly address that question.

3. The government has been working diligently to respond to KVK's privilege claims relating to more than 87,000 items, which may require a document by document review. The majority of those items remain in dispute, and as a result, the litigation before the Special Master is ongoing and extensive. To properly respond to KVK's claims, the government now believes it is necessary to add one or more attorneys from OCC who have specialized knowledge of the requirements that apply to KVK under the Food, Drug, and Cosmetic Act ("FDCA"). These requirements are related to many of KVK's privilege claims and are particularly relevant to anticipated briefing on crime-fraud arguments. Specifically, the government anticipates alleging there is a reasonable basis to find that KVK misled the FDA regarding KVK's intentions to come into compliance after receiving warning letters. OCC's detailed understanding of the complex FDCA law regarding KVK's representations under the FDCA, and how those representations fit within the FDA's compliance program will inform evaluations of whether crime-fraud renders KVK's attorney-client privilege and work product protection claims invalid.

4. Granting this motion is in the interests of justice and would not unfairly prejudice KVK. If permitted, the government intends to add any OCC attorney seamlessly in its filter review process, and it will not require any additional time to do so. Addressing KVK's claims with this technical assistance will thus promote efficiency, accuracy, and a fair resolution of KVK's claims.

5. Granting this motion would leave the Filter Review Order's current processes and protections in place, would not violate any provisions of law, and, in accordance with Federal Rule of Criminal Procedure 6(e)(2)(B), OCC attorneys will not be reviewing any matter occurring before the Grand Jury.

6. On several occasions beginning on April 14, 2022, the government advised KVK of its need for OCC participation and sought KVK's position on this ministerial request. KVK

advised the government on May 25, 2022, that it opposes this motion.

WHEREFORE, for the foregoing reasons, the Government respectfully requests that this Court grant its Motion to allow attorneys from the Food and Drug Administration's Office of Chief Counsel to serve as members of the Filter Team.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have served a true and correct copy this motion by electronic filing,
which provides notice to all attorneys of record in this matter.

/s _____
Speare I. Hodges
Trial Attorney
Consumer Protection Branch

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[PROPOSED] ORDER

This matter comes before the Court on consideration of the Government’s Motion to Modify the Court’s Order Related to Filter Team Composition, the Court having considered the motion, any response thereto, and argument upon it, if any, the Court finds the motion is well-taken.

Therefore, this ____ day of ____, 2022, it is hereby ORDERED that:

1. The motion of the Government to modify the Court’s Order, Doc. #87, to allow attorneys from the Food and Drug Administration’s Office of Chief Counsel to serve as members of the filter team is GRANTED.

2. Section I of the Court’s Order shall be modified as such:

The government filter team (hereinafter, “Filter Team”) will be comprised of Department of Justice (“DOJ”) attorneys, contract attorneys and attorneys employed by the Food and Drug Administration’s Office of Chief Counsel acting under the supervision of DOJ attorneys, and designated support staff acting at their direction, none of whom is a member of the Prosecution Team. The Filter Team’s privilege¹ review will be conducted solely by attorneys. The Filter Team will retain and may review all Seized Materials but may not discuss contents with or release them to the Prosecution Team, except as provided in this Order.

BY THE COURT:

J. Harvey Bartle III